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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,530	01/23/2004	Minoru Sano	NPR-135	5543

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EXAMINER

MCCORKLE, MELISSA A

ART UNIT	PAPER NUMBER
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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,530	Applicant(s) SANO ET AL.	
	Examiner Melissa A. McCorkle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 4-7, filed 01/22/2007, with respect to the rejection(s) of claim(s) 1 and 3 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art, cited below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhard et al (6,331,174) in view of Kaufhold Jr et al (5,125,898).

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5. Reinhard discloses all of applicant's basic inventive concept of a prefilled syringe [figure 3A] with the exception of using a Luer tip for connection of the injection needle. Kaufhold shows the use of a luer lock tip [see abstract] used with a syringe to be old in the medical delivery devices art. At the time of applicant's invention it would have been obvious to one of ordinary skill in the art from the teaching of Kaufhold [see abstract] to use a luer tip for the purpose of using it in connection with the seal/gasket to force the needle inside the plunger, for added safety.

6. Regarding claim 1, Reinhard discloses a prefilled syringe [column 2, line 61] comprising a shoulder portion [where barrel turns into nozzle, fig 3A at (5)], a barrel 1 closed by the shoulder portion and having an open proximal end [figure 2], and a gasket 4 inserted adjacent to the open proximal end of the barrel in a fluid tight manner while being freely slideable [col 4, line 61], a medication [col 2 line 59] being contained inside the barrel, wherein the barrel has a multilayer structure [col 3 line 66 – col 4 line 27, and column 6 line 17-38 and figure 3A] in which an innermost layer and an outermost layer are both made of a polyolefin resin [column 4, line 11], and an intermediate layer 14 [see col 6 line 28+] is sandwiched by the innermost and the outermost layer and is composed of at least one layer made of a resin excelling in an oxygen and/or water vapor property [col 5 line 25], and further wherein the intermediate layer is formed up to a vicinity of a surface of the tip of the luer tip, and is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel [[figure 3A].

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7. Regarding claim 3, Reinhard discloses a prefilled syringe comprising a shoulder portion, a barrel 1 closed by the shoulder portion and having an open proximal end [figure 2], and a gasket 4 inserted adjacent to the open proximal end of the barrel in a fluid tight manner while being freely slideable [col 4, line 61], a medication [col 2 line 59] being contained inside the barrel, wherein the barrel has a multilayer structure [col 3 line 66 – col 4 line 27, and column 6 line 17-38 and figure 3A] in which an innermost layer and an outermost layer are both made of a polyolefin resin [column 4, line 11], and an intermediate layer 14 [see col 6 line 28+] is sandwiched by the innermost and the outermost layer and is composed of at least one layer made of a resin excelling in an oxygen and/or water vapor property [col 5 line 25], and further wherein an end of the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion [fig 3A], the shoulder portion formed with the polyolefin resin has a thickness sufficient to exert an oxygen and/or water vapor barrier property [col 6 line 48+, shoulder portion is at nozzle, nozzle is constructed of same], and the luer tip is sealed by a cap 7 having a barrier property [col 5 line 17.]

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9:00am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
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Melissa A McCorkle
Examiner
Art Unit 3763

/MAM/
06/05/2007